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| --- |
| Under this waiver, the investigator is still **required to provide informed consent** to the potential subject, but the subject’s signature is not required on the form.Along with this waiver request, you must submit a consent statement or written script that will be provided or presented to the potential subject. The consent statement or script must contain all the elements of informed consent. |
| **Project Title:**  |       |
| **Principal Investigator(s):** |       |
| **Date of Submission:** |       |
|  |
| **Submission Instructions:** * Read the criteria for waiver or alteration of written documentation of consent
* Select the appropriate reason for request
	+ Check the box for 1, 2, or 3
* Submit one copy with IRB Application
 |
| **Criteria for Waiver or Alteration of Written Documentation of Informed Consent:**1. *The research involves no more than minimal risk to the subjects.*
2. *The research could not practically be carried out without the waiver or alteration.*
3. *If the research contains identifiable private information or identifiable biospecimens, the research could not be carried out without using such information or biospecimens in an identifiable format*
4. *The waiver will not adversely affect the rights and welfare of the subjects.*
5. *The subjects will be provided with additional pertinent information after participation.*
 |
| **Request for waiver of written documentation of informed consent is based on:** |
|  [ ]  1. |  |
| A signed consent form is the only record linking the subject to the research |
|  | Explain: |       |
|  | AND |
| The principal risk would be potential harm from a breach of confidentiality |
|  | Explain: |       |
|  | AND |
| Each subject (or legal representative) will be asked if they want to sign a Consent Form |
|  | Explain how this will be done: |       |
|  | AND |
| The research is **NOT** subject to FDA regulation |

|  |  |
| --- | --- |
| [ ]  2.  |  |
| The research presents no more than minimal risk of harm to subjects |
|  | Explain: |       |
|  | AND |
| The research involves no procedures for which written informed consent is normally required outside of the research contexts |
|  | Explain: |       |

|  |  |
| --- | --- |
| [ ]  3.  |  |
| The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm |
|  | Explain: |       |
|  | AND |
| The research presents no more than minimal risk of harm to subjects |
|  | Explain: |       |
|  | AND |
| There is an appropriate alternative mechanism for documenting that informed consent was obtained |
|  | Explain how this will be done: |       |

IRB Office use only:

|  |  |  |  |
| --- | --- | --- | --- |
| Waiver approval date: |       | IRB Identification Number: |       |

|  |  |  |
| --- | --- | --- |
| Approved by: |       |  |